Management of study-paid research related injury

PAT-006
Effective date: 01/Nov/2020

I. SCOPE

Clinical research studies conducted by Loyola University Chicago (LUC) or in a Loyola Medicine facility for which the study participant is promised treatment of research related injury (RRI) free of charge in the consent form, or the study agreement states LUC or Loyola University Medical Center will be reimbursed for the cost of treatment of RRI. If either document states treatment of RRI is paid for by the study, the study is responsible for the cost of the treatment. This SOP provides the steps necessary after the identification of a potential RRI through to confirmation of RRI.

II. DEFINITIONS

Research Related Injury (RRI): an injury or illness suffered by a participant in a research study that is:

a. Directly related to the study or a portion of the study, for example the study drug or study device;
b. Not attributable to the Study Team's or treating hospital's negligence, recklessness, or willful misconduct; and
c. Not the result of a pre-existing condition or the normal progression of the participant's disease.

For each research study, the IRB-approved consent form and the study's agreement (contract, grant, or other) is/are the governing document(s) on what is considered an RRI.

III. PROCEDURES

a. The steps required in this SOP are to be completed in addition to and in parallel with steps required by the IRB of record and the study sponsor notifications.
b. The principal investigator (PI) or his/her designee ("Study Team") identifies a study participant may have experienced a RRI.
    i. The Study team reviews the IRB-approved consent and the study agreement, if applicable, to learn if:
        1. The study is to pay for RRI. If it is not, no further action is needed in this SOP.
        2. The agreement requires the study sponsor agree with the PI's determination that the event meets the definition of RRI.
            a. If it does, continue the processes as described in this SOP in parallel with requesting the study sponsor's agreement.
            b. If there is not agreement between the PI and study sponsor in the determination of RRI, notify the LUC Vice Provost of Research and Senior Director of Research Administration.
    ii. The SOP should continue to be followed until there is confirmation the event is not a RRI.
    iii. If the event was treated at a Loyola Medicine facility (Loyola University Medical Center, Gottlieb Memorial Hospital, MacNeal Hospital, or an ambulatory site of one of those hospitals), the Study Team:
        1. Sends an email to Revenue Integrity Research Billing (RI-RB) with the following information:
            a. Notification that the participant was treated for an event that may be or is confirmed to be a study-paid RRI.
            b. The LU of the study in which the patient is participating.
            c. The participant's MRN and name.
            d. The date of service the participant received treatment.
            e. If the event is resolved (all treatment for the event already provided) or if it is ongoing.

2. RI-RB stops any charges from being billed to the participant or the participant's insurance via Epic.
3. RI-RB identifies third parties that may have been involved with the treatment of the event and informs the Study Team.

c. As soon as the event is confirmed to be RRI:
   i. The Study Team notifies the study participant that:
      1. the event was determined to be RRI
      2. the treatment related to the RRI is paid for by the study
      3. he/she should notify the Study Team if he/she receives an Explanation of Benefits or bill for the treatment so the Study Team can notify the appropriate parties to correct.
   ii. The Study Team notifies RI-RB and the study is billed for the RRI.
      1. RI-RB transfers charges for the treatment of the RRI to the study account in Epic and invoices the Study Team per SOP FIN-004 Invoicing for research related patient care costs.
      2. The Study Team invoices the sponsor for the additional charges incurred for the treatment of the RRI.
      3. The Study Team pays the Epic research statement per usual process.
   iii. If the RRI was treated at an outside (non-Loyola Medicine) facility or by outside (non-Loyola Medicine) providers:
      1. The Study Team reviews the study agreement to understand if the outside facility/providers may bill the sponsor directly or if LUC needs to pass through the bills.
      2. The Study Team contacts the treatment facility and/or provider and notifies them that the services provided to the participant for the treatment of the RRI are not to be billed to the participant or the participant's insurance.
      3. If the sponsor pays the outside facility/provider directly, the Study Team provides the sponsor contact information to the outside facility/provider.
      4. If LUC passes through the bills, the Study Team provides the Study Team's billing information to the outside facility/provider.
         a. When the invoice from the outside facility/provider is received, the Study Team invoices the sponsor for the total of the invoice.
         b. The Study Team pays the outside facility/provider's invoice.

IV. REFERENCES

a. SOP FIN-004 Invoicing for research related patient care costs

V. APPROVALS

Katherine van Muus 10/15/2020
LUMC Manager, Clinical Research (or designee) Date

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LUC Senior Director, Clinical Research Office (or designee) Date